

specification does not describe a sufficient number of species which are representative of the genus. Applicants respectfully assert, however, that the specification as filed satisfies the written description requirement for the claims.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the invention at the time the application was filed (Guidelines for the Examination of Patent Applications Under 35 USC 112, P1, Written Description Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001) ("Written Description Guidelines"). Possession may be shown in a variety of ways including a description of distinguishing identifying characteristics sufficient to show that the applicant was in possession of the invention (Written Description Guidelines at 1104). An actual reduction to practice is not required (Id.). There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed (Written Description Guidelines at 1105). Rejection of an original claim is meant to be a rare occurrence (Id.)

With particular respect to a claim drawn to a genus, the written description requirement for a claimed genus may be satisfied through description of a representative number of species by a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus (Written Description Guidelines at 1106). There may be situations where one species is a "representative number of species" (Id.). Satisfactory disclosure depends on whether one of ordinary skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed (Id.). In the present patent application, as filed, the claimed

invention is described in sufficient detail to allow one of ordinary skill in the art to recognize that applicants had possession of a compound and/or inhibitor having the distinguishing characteristics of decreasing functional levels of CD63. One skilled in the art, possessed with the information contained in the application and known in the art, could screen for other suitable compounds and/or inhibitors for use in the invention (present specification, page 11, lines 24-27) In particular, see page 12, lines 1-14 of the present specification which sets out the procedure for a method for screening for agents which have the ability to modify CD63 function. "Functional" expression refers to the synthesis and any necessary post-translational processing of a CD63 molecule in a cell so that the CD63 is active (specification, page 11, lines 30-34). Accordingly, the rejection of claims 1-10 for lack of written description is improper and should be withdrawn.

The rejection of claims 1-10 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed.

In order for claims to be enabled, the specification, when filed, must contain sufficient information as to enable one skilled in the art to make and use the claimed invention. (Manual of Patent Examining Procedure ("MPEP") 2164.01). As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, the enablement requirement is satisfied. (In re Fisher, 427 F.2d. 833, 839, 166 USPQ 18, 24 (CCPA 1970); MPEP 2164.01(b)). In determining whether a patent application is in compliance with the enablement requirement, the PTO will consider whether one of ordinary skill in the art could practice the invention without undue experimentation. In re Wands, 858 F.2d. 731, 8 USPQ2d 1400 (Fed. Cir. 1988)).

The claims of the application set forth methods which decrease levels of functional CD63 present within cells. These claims are fully enabled. One of ordinary skill in the art could practice the invention, whether *in vitro* or *in vivo*, by following the procedures as set out in the present specification. Accordingly, the rejection is improper and should be withdrawn.

In view of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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Date

Karla M. Weyand
Karla M. Weyand
Registration No. 40,223

Braman & Rogalskyj, LLP
P.O. Box 352
Canandaigua, New York 14424-0352
Tel: 716-626-5380
Fax: 716-626-5384

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Appendix: Marked up Claims

5. (Amended) A method of treating [or preventing] human immunodeficiency virus infection in a subject, the method comprising administering to the subject an amount of a compound effective to decrease levels of functional CD63 in cells of the subject.